Testimony Before
U.S. Senate Forum Convened by Senator Carl Levin and Senator Orrin Hatch
Buprenorphine in the treatment of opioid addiction: successes and the impediments to expanded access
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Good morning and I want to thank you, Senator Levin and Senator Hatch, for convening this forum and for inviting the Substance Abuse and Mental Health Services Administration (SAMHSA) to participate.

Many advances have been made in improving access and treatment for those seeking medication-assisted therapy since the passage of the Drug Addiction Treatment Act of 2000 (DATA 2000) – but there is still much that can be done to help those who misuse or abuse opiates. Prior to DATA 2000, opioid agonist therapy was only available in methadone maintenance programs. The only office-based treatment available was oral Naltrexone, which was not often selected by opioid dependent patients because, while it blocks the effects of opioids or alcohol, it was difficult to get people to come back for refills.

The enactment of DATA 2000 promised millions of Americans the opportunity to obtain agonist treatment through the privacy of a physician's office, in addition to federally-certified opioid treatment programs. The approval of Suboxone and Subutex increased the availability of effective medication-assisted treatment for opioid use disorder and gave substance to DATA 2000. More recently, the Food and Drug Administration (FDA) approved two new formulations of buprenorphine/naloxone: Zubsolv® and Bunavil® -- the second of which is not yet available. These two new formulations will provide prospective patients with more choices that may make treatment more acceptable. In addition, the availability of the monthly injectable Vivitrol® for relapse prevention of opioid use provides an alternative to agonists. Its treatment shows promise in attracting patients who otherwise might not benefit from opioid addiction treatment.

SAMHSA is responsible for overseeing the regulatory compliance of certified Opioid Treatment Programs (OTPs), which use methadone and/or buprenorphine for treatment of opioid addiction. Currently, there are 1,311 OTPs. In addition, SAMHSA registers physicians who intend to prescribe or dispense buprenorphine for management of opioid addiction – a process that is coordinated with the Drug Enforcement Administration (DEA). According to the Drug Addiction Treatment Act of 2000 as amended, a physician may not treat more than 30 or 100

patients at any one time. As of June 13, 2014, there were 25,388 active DATA-waived physicians – 7,892 of whom are authorized to prescribe to up to 100 patients. A total of over 900,000 patients are served by these physicians.

Because the DATA legislation without regulations does not allow the Department of Health and Human Services to exempt a physician from exceeding the 100 patient cap, SAMHSA has encouraged physicians to consider applying for an Opioid Treatment Program certification under 42 CFR Part 8 rules. The Department is also considering the need for changing the cap for providers that are currently certified.

The lack of sufficient access to buprenorphine certified physicians in some underserved areas is a continuing challenge. DATA 2000 only permits physicians to prescribe medications for the treatment of opioid use disorder. Therefore, a nurse practitioner or physician assistant, who may be permitted under federal and state statutes to prescribe a Schedule III product for treatment of pain, is not allowed to prescribe buprenorphine products for managing addiction.

SAMHSA has worked with state substance abuse agencies, federally qualified health centers, and the Indian Health Service to provide training for primary care physicians in order to raise the awareness of buprenorphine treatment. Many of SAMHSA's training modules have been adapted to utilize webinars, online education, and other technology to increase the ability to reach practitioners located in rural areas. In addition, SAMHSA funds the Physician Clinic Support System for buprenorphine. This program was expanded recently to include other medications for the treatment of opioid use disorder. The expanded program – called PCSS Medication-Assisted Treatment – is designed to educate current and future prescribers regarding appropriate prescribing practices for pain and other medications subject to abuse. The PCSS is actively engaged in providing continuing medication education to primary care providers, including those interested in prescribing buprenorphine.

SAMHSA has also been assisting the Centers for Medicare and Medicaid Services (CMS) to develop and release an Informational Bulletin for states regarding the use of and inclusion of buprenorphine in state Medicaid plans. Through these and other ongoing efforts SAMHSA continues to work toward ensuring those who need medication-assisted treatment receive it, and those physicians who want to provide those services are able to do so.

Impediments to those efforts include the inability of non-physicians – such as nurse practitioners – to prescribe buprenorphine, the managed care strategies of some private and public insurance plans that make it difficult for some patients to participate in treatment, and the current patient number limitations. Also, some states have proposed regulations that – if enacted – might make it difficult for some patients to continue participating in treatment. My colleague, Dr. McCance-Katz, is going to address in more detail the barriers that exist in expanding the number of DATA-waived physicians, so I defer to her on this.

Thank you.

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